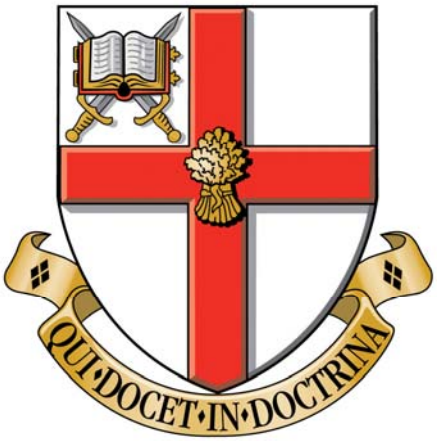

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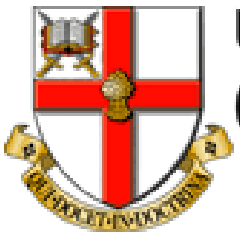

University of Chester

Department of Clinical Sciences

Master of Science
In
Cardiovascular Rehabilitation

An exploratory study to determine if younger patients' with implantable cardioverter defibrillators have an improved quality of life following cardiac rehabilitation

"Dissertation submitted in accordance with the requirements of University of Chester for the degree of Master of Science."

Andréa Grieger

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An exploratory study to determine if younger ICD patients' with implantable cardioverter defibrillators have an improved quality of life following cardiac rehabilitation

Abstract

Background

The quality of life and anxieties of young patients with implantable cardioverter defibrillators (ICD) are not clearly understood. A small number of studies have looked at both physical and psychological issues in this group however not by evaluating attendance and outcomes of ICD patients' participating in cardiac rehabilitation (CR).

Aims and objectives

The study aims to establish whether a CR programme offered to young ICD patients (less than 50 years of age) helps improve their quality of life and reduces stress and anxiety levels. A comparison was made to a group of young ICD patients who had not yet completed a CR programme.

Methods

The sample size was twenty ICD patients with inherited cardiac conditions who had an ICD implanted in the last eighteen months. Ages ranged from 23-49 years, mean age was 40 (± 7.83). The CR group (n=10) had enrolled on an eight week CR programme at Imperial College Healthcare NHS Trust and completed a quality of life questionnaire and Hospital Anxiety and Depression Scale (HADS) at baseline and after the programme. The non-CR group (n=10) were asked to complete the same questionnaires. Retrospective questionnaire data was analysed pre and post CR using repeated measures and compared with prospective data collected from the non-CR group. Quality of life components included physical fitness, feelings, daily activities, social activities, pain, change in health, overall health, social support and quality of life.

Results

In total five patients in the CR group completed the CR programme within the study timeframe and 80% of patients in the non-CR group returned the questionnaires. None of the CR group quality of life scores were found to be statistically significant following CR. There was a reduction between pre and post questionnaire median scores in components 'quality of life' (12.5%), 'daily activities' (25%), and 'physical fitness' (25%). A reduction of 14.29% was observed in the CR group depression scores, however differences in both anxiety and depression scores were not found to be significant ($p=0.680$, $p=0.06$ respectively). Post CR scores and non-CR group quality of life scores were not significantly different.

Conclusion

This exploratory study identified areas of quality of life where younger ICD patients experience problems and how CR may assist them in their initial recovery after ICD implant. A reduction was found in depression scores following CR, however it is not clear whether CR improves quality of life for this population. There may be scope for specific ICD follow up in the future as these patients currently have access to specialist advice from healthcare professionals within Cardiology.

Declaration

"This work is original and has not been previously submitted in support of degree qualification or other course".

Signed ……(Andrea Grieger)……..

Date …19th November, 2012……

Contents

List of figures

List of tables

Abbreviations

CR	Cardiac Rehabilitation
ICD	Implantable Cardioverter Defibrillator
HADS	Hospital Anxiety and Depression Scale
SADS	Sudden Arrhythmic Death Syndrome
HCM	Hypertrophic Cardiomyopathy
DCM	Dilated Cardiomyopathy
ARVC	Arrhythmogenic Right Ventricular Cardiomyopathy
CPVT	Catecholaminergic Polymorphic Ventricular Tachycardia
LQTS	Long QT Syndrome
ATP	Antitachycardia pacing

Chapter 1 – Introduction and Literature Review

In recent years there has been an increase in the number of individuals diagnosed with inherited cardiac conditions such as hypertrophic cardiomyopathy (HCM), dilated cardiomyopathy (DCM), Long QT syndrome (LQTS), Brugada syndrome, Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC) or Catecholaminergic Polymorphic Ventricular Tachycardia (CPVT) (Behr, 2009). Following careful risk stratification by specialist cardiology clinics a proportion of these patients deemed to be at high risk of dangerous ventricular arrhythmias are recommended to have an implantable cardioverter defibrillator (ICD). As this treatment has shown to reduce mortality newer joint guidelines for ICD implantation were published by the American College of Cardiology, American Heart Association and the European Society of Cardiology (Zipes et al. 2006).

The occurrence of Sudden Arrhythmic Death Syndrome (SADS) predominantly affects young males however females can also be at risk (Behr et al. 2007). An estimated 500 potential SADS cases per annum in England were thought to be eight times lower than official national mortality statistics figures when the incidence of SADS was surveyed through coroners' jurisdictions in England (Behr et al. 2007). Figures from the charity Cardiac Risk in the Young reported at least twelve sudden cardiac deaths a week in the UK in those aged under 35 years of age (Cardiac Risk in the Young 2008). Families with SADS carry some form of genetic cardiac disease which puts them at risk of further sudden deaths and should therefore be a certifiable cause of death (Behr et al. 2007). Currently specialised cardiological evaluation of families who may have an inherited cardiac condition occurs in a clinic in Imperial College Healthcare NHS Trust with a multidisciplinary team of cardiologists, arrhythmia nurse specialists and cardiac physiologists.

1.1 Causes of Sudden Cardiac Death in Younger Adults

Sudden Cardiac Death (SCD) in younger adults may be caused by one of many structural or electrophysiological abnormalities.

1.1.1 Hypertrophic Cardiomyopathy

Hypertrophic cardiomyopathy is a disease of the myocardium. It is a genetic condition passed on through families by a 50/50 chance caused by an autosomal dominant gene mutation in one or more genes. About 1 in 500 of the UK population has the condition with most people experiencing few if any symptoms (Watkins, Ashrafian & McKenna 2008). The main abnormality is with thickening of the myocardium usually the left ventricle and evidence of myocardial cell disarray. If the ventricle walls increase in thickness there can also be some obstruction of the mitral valve leaflets. Scarring can be identified on cardiac MRI scanning, if present this adds to risk for sudden dangerous arrhythmias.

1.1.2 Dilated Cardiomyopathy

Dilated cardiomyopathy (DCM) occurs due to a genetic mutation. The left ventricle becomes dilated and the myocardium becomes weak and thin causing left ventricular dysfunction. This can lead to pulmonary oedema and ankle oedema and subsequent heart failure symptoms. Commonly this condition develops slowly and symptoms may be quite severe before a diagnosis is made. There may also be mitral regurgitation. As the myocardial cells become stretched there is an increased risk of arrhythmias and perhaps a recommendation for implanting an ICD. Most cases are idiopathic however viral, autoimmune, genetic, and environmental causes have been speculated. Viral infection such as viral endocarditis, myocarditis, parasites and protozoa can also increase the risk of DCM. Recreational drug use of cocaine has been linked to the condition as well (McKenna, W. & Elliott, P. 2009).

1.1.3 Arrhythmogenic Right Ventricular Cardiomyopathy

This is also an inherited cardiac condition caused by a mutation in one or more genes. Those diagnosed with Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC) have proteins between the myocardial cells which have not developed properly. When the heart is under stress for example during exercise the cells become damaged and detached. These myocardial cells become fibrous and cause scarring. Fatty deposits build up to try and repair the damage. The condition is normally progressive and can sometimes involve the left ventricle.

1.1.4 Long QT Syndrome

This genetic condition is known as an ion channelopathy where a mutation in the DNA affects how potassium ions move in and out of cardiac myocardial cells. It is one of the most common and best understood channelopathies and occurs in about 1 in 2,000 people (Behr, 2009). A small proportion of people with Long QT Syndrome (LQTS) have abnormalities in the sodium channels. A resting electrocardiogram (ECG) can show a prolonged QT interval however sometimes further cardiac investigations are needed to show clear evidence of the condition. With potassium channel LQTS sudden death can be related to exercise or when the person has been startled or suddenly woken. The sodium channel form of LQTS is usually associated with death during sleep.

1.1.5 Brugada Syndrome

Brugada syndrome was identified in the early 1990's and is not a common inherited cardiac condition in the western world; it appears to be more prevalent among young men in South East Asia. The syndrome is associated with mutations in the sodium channel which can provoke sudden ventricular arrhythmias causing blackouts or sudden death during sleep. Changes on ECG which are characteristic of Brugada Syndrome are sometimes only visible through a provocation test using an antiarrhythmic drug called Ajmaline.

1.1.6 Catecholaminergic Polymorphic Ventricular Tachycardia

This rare condition known as CPVT is found in young people and children. It has been associated with two genes which make proteins that regulate the release of calcium ions in cardiac cells, the human ryanodine receptor and calsequestrin. An increase in intracellular calcium levels occurs resulting in arrhythmias, polymorphic ventricular tachycardia, more often with exercise; this may lead to collapse and sudden death. It appears to cause more blackouts in males more than females.

1.2 Cardiac Rehabilitation and ICD patients

Historically ICD patients have not been routinely referred to a cardiac rehabilitation service. In the last few years ICD patients attending cardiac rehabilitation tend to be those with a history of myocardial infarction or heart failure. These groups of patients are generally older and have may have limited exercise tolerance or physical abilities. Amongst the younger age group diagnosed with inherited cardiac conditions most are not referred for cardiac rehabilitation as not all services have the resources, funding and specialist staff to support these ICD patients.

There are established benefits of regular exercise for patients with cardiovascular disease, as well as healthy individuals. Intermittent high intensity exercise however may precipitate myocardial infarction and sudden cardiac death (Mittleman et al. 1993, Willich et al. 1993, Albert et al. 2000). Regular physical activity has shown to cause a protective effect against these cardiac events (Tanasescu et al. 2002). In essence cardiac rehabilitation programmes increase exercise capacity, decrease mortality and improve quality of life for cardiac patients (Hedback, Perk, & Wodlin 1993, Belardinelli, Georgiou, Cianci, & Purcaro 1999) and potentially could help younger ICD patients recover following ICD implantation.

Patients with ICD's who participated in organised cardiac rehabilitation programmes have been found to regularly engage in more vigorous exercise than patients who did not attend

a programme. They also received less appropriate shocks overall and were found to suffer no ICD discharges during exercising in a CR programme which suggests a protection against exercise induced arrhythmias (Davids, McPherson, Earley, Batsford, & Lampert 2005).

1.3 Primary prevention ICD implant

Looking at how the concept of primary prevention ICD's evolved first goes back to one of the largest ICD randomised controlled trials, the Mulitcentre Automatic Defibrillator Implantation Trial MADIT-I (Moss et al. 1996). ICD's were compared with conventional medical therapy for those with coronary artery disease and high risk of ventricular arrhythmia. A significant survival benefit was found with ICD implantation, the trial was terminated early.

The following year the AVID trial (Antiarrhythmics versus implantable defibrillators investigators, 1997) compared antiarrhythmic drug therapy to ICD's. They concluded that the ICD was superior to antiarrhythmic drug therapy in prolonging survival among patients resuscitated after symptomatic sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) causing haemodynamic compromise. Recommendation was made for ICD's to be offered as first line treatment for these patients.

Implanting an ICD for prophylactic purposes eventually arose from the Mulitcentre Automatic Defibrillator Implantation Trial MADIT-II (Moss et al. 2002). In this trial patients with left ventricular dysfunction (ejection fraction less than 30%) or previous myocardial infarction (n=1232) were given prophylactic ICD's or conventional medical therapy, this trial was terminated early as again there was a high survival rate in the ICD arm of the trial. As this is one large trial with risk stratification tools such as electrophysiology testing, measuring ejection fraction and ambulatory holter monitoring to determine appropriate patient selection for ICD, multiple discussion points were raised regarding implanting ICD's for prophylactic purposes, overuse of the device and increase in healthcare spending

(Reynolds & Josephson 2003). The National Institute of Clinical Excellence (NICE) published guidance 'Implantable Cardioverter Defibrillators for the treatment of arrhythmias' in 2000 which was reviewed and published again in 2006 (National Institute for Health and Clinical Excellence 2006) highlighting criteria which guides the medical profession in the UK on implanting ICD's. Positive results from the MADIT-I and MADIT-II trials along with improved technology has meant a rapid increase in the use of ICD's for prophylactic purposes especially in those with reduced left ventricular function or inherited cardiac conditions at risk of ventricular tachycardia or ventricular fibrillation.

The National Institute of Clinical Excellence back in 2000 stated in their document 'Guidance on the use of implantable cardioverter defibrillators for arrhythmias' there should be a rehabilitative approach to aftercare for ICD patients which should include psychological preparation for living with an ICD. Specialist training for health care professionals giving this preparation to patients should be important along with appropriate timing of the session. Most device implants are performed on a planned admission yet may also be done on an emergency admission following cardiac arrest. Currently arrhythmia nurse specialists provide counselling and support in implant centres however the coordination within the Cardiology team is paramount if the patient is to gain extra support or advice from the wider team ie. psychologist, exercise specialist within the early post implant period.

1.4 Psychological benefits of cardiac rehabilitation

ICD patients show both psychosocial and physiological issues, the most common being anxiety, depression, fear and resuming physical activity (Sears & Conti 2002, Hamilton & Carroll 2004, Thomas et al. 2006, Dunbar et al. 2009). Therefore the established benefits of cardiac rehabilitation in coronary heart disease (CHD) patients in decreasing morbidity and mortality as well as helping psychological issues (Brugemann et al. 2007) should be

recognised and applied to assisting ICD patients through their recovery. Prevalence of depression in patients following a coronary event has been high between 20 and 45% (Wenger, 2008) which highlights the support needed for those who have experienced an unexplained cardiac arrest and subsequently had an ICD implanted. The benefits of educational sessions to look at misconceptions and concerns surrounding a cardiac event (Brugemann et al. 2007) and having a clinical psychologist as part of the team means cardiac rehabilitation can promote well-being and motivate patients to return to appropriate and satisfactory occupations (Wenger 2008). The British Association for Cardiovascular Prevention and Rehabilitation (2012) standards highlight prevention, behaviour change and education as the core of CR stating implantable device patients may need additional expertise during CR and in addition liaison with specialist cardiac services.

The World Health Organisation (1997) defines quality of life as 'individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.' They state it is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment.

1.5 Review of the literature

As ICD technology has improved over the years it is known to be very effective in treating life threatening arrhythmias. The concept of living with the device and the actual adjustment to living with it is not always an easy transition for patients. To date the majority of studies, mainly quantitative, have concentrated on patient groups over 40 years of age and few have explored how younger ICD patients cope with everyday life. Long-term outcomes of ICD patients are still to be deduced. In summary younger adults' experiences are very different and need further examination (Sears & Conti 2002). It has been highlighted they experience psychosocial responses after ICD implantation such as anxiety, depression, fear, anger, stress, body image and sexual concerns (Dunbar et al. 2009).

Many patients also see the reputation of the ICD as a 'shock box' which in turn is a significant source of anxiety. Any types of measurement or psycho-educational intervention given by a multidisciplinary team should focus on patient acceptance of the device (Sears & Conti 2002). They stipulate interdisciplinary studies including cardiology, psychology, nursing and cardiac rehabilitation specialists are needed to guide best clinical practice and furthermore suggest routine consideration of psychosocial needs be integrated into the clinical care of ICD patients. Addressing such needs is not always part of routine care in implant centres.

Advanced ICD technology has helped the issue surrounding risk of inappropriate shocks. Improved sensing and therapy options such as antitachycardia pacing (ATP) can reduce the number of shocks a patient receives. ICD patients are still likely to need some attention to psychological adjustment whether they receive appropriate or inappropriate therapies from the device.

1.5.1 Quality of Life

In the last ten years assessing quality of life and anxiety of ICD patients has mainly been examined with the use of questionnaires with short follow up periods of up to 12 months post implant. The impact of a shock has been a major factor affecting quality of life and anxiety; Pelletier, Gallagher, Mitten-Lewis, McKinley & Squire (2002) examined this issue using the SF-36 quality of life questionnaire (Ware, Snow, Kosinski, & Gandek 1993) which is a popular and reliable measurement tool. To further assess experiences of shock, driving status and device complications a specially designed questionnaire following patient interviews was developed and used in the study; the reliability and validity of this tool is not apparent. The cohort (n=74) were either cardiovascular disease patients or those with a history of ventricular tachycardia and predominantly male (84%). Results revealed the impact of an ICD over the first 12 months caused a significant reduction in 'general health' and 'social function' scores ($p<0.05$). This deterioration of quality of life within this age group (mean age 60 years) implies the patient and their families need continuing support during the first year and beyond. If longer term support is to be available to ICD patients in the future more investment into resources to aid this would be required by healthcare services.

Hamilton and Carroll (2004) also investigated quality of life in a group of ICD patients (n=70) with a past medical history of myocardial infarction, heart failure or previous coronary artery bypass graft. The older age group were found to be less physically active, less satisfied with their physical functioning and had slightly more anxiety at 6 and 12 months than their slightly younger counterparts. The younger ICD recipients (mean age 51 years) demonstrated improvement over 12 months in the perception of their physical adjustment ($p=0.03$) and a dramatic reduction in anxiety at 6 months with a slight increase at 12 months ($p=0.0001$).

A review of ICD patients' quality of life and psychological status (Thomas et al. 2006) summarised that younger patients (less than 50 years of age) were deemed to be at higher risk of psychological distress and poor quality of life after ICD implantation yet physical limitations were less of a problem. These patients received an ICD as secondary prevention treatment not primary prevention. One suggestion made was that programmes developed by nurses and encouraging patients to discuss their experiences in a group environment may decrease depression and improve quality of life. There are few ICD support groups nationally some of which are based in NHS establishments or community based supported by cardiac charities. For this type of support to be successful there has to be appropriate times and accessible venues for younger working patients to attend.

A large longitudinal prospective study by Kamphuis et al. (2003) examined quality of life in relation to whether a shock was received or not. Questionnaires used were the quality of life RAND-36 designed for cardiac patients (Hays, Sherbourne, & Mazel 1995), the Heart Patient Psychological Questionnaire (HPPQ), a State–Trait Anxiety Inventory STAI (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs 1983) and Centre for Epidemiologic Studies Depression Scale (CES-D). They concluded that overall quality of life did not change irrespective of whether the patient received a shock or not. There were however higher levels of anxiety in the group that experienced a shock compared to the group that did not. Frequency of inappropriate shocks has reduced as device programming has improved since this study therefore levels of anxiety related to shocks may be less relevant.

Kamphuis et al. (2004) also published qualitative data of a small group (n=21), mean age 58.3 years exploring how the first year of living with an ICD affected perception of life. The main categories arising from interviews at 1, 6 and 12 months post implant were physical deterioration, cognitive changes, perceived social support, dependency, contact with the doctor, confrontation with mortality and uncertainty surrounding having a shock.

Significant issues in the first year included anxiety, uncertainty, disappointment, frustration, unexpected barriers, acceptance of and dependency on the ICD. Regaining physical health was important in the first few months for this group and therefore highlights that involvement in a CR programme could support patients with improving quality of life.

One of the largest studies of quality of life with ICD therapy was an analysis by Schron et al. (2002) from the Antiarrhythmics Versus Implantable Defibrillators trial (AVID investigators 1997). This was a secondary prevention trial that was stopped prematurely as there was a significant survival rate in the ICD arm of the trial. The ICD arm and antiarrhythmic therapy arm showed similar changes in quality of life questionnaire (SF-36) physical and mental component scores. The occurrence of one or more ICD shocks was significantly associated with reductions in both physical functioning and mental well-being. Conclusions drawn from the AVID analysis were in the absence of shock therapy ICD's were well tolerated and did not reduce the quality of life of recipients.

Mark et al. (2008) examined the effects of primary prevention ICD therapy on health-related quality of life in the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT). looked at patients with life-threatening arrhythmias versus stable heart failure patients and found a significantly lower quality of life data collection rate in AVID (83% at baseline and 61% at one year).

A fear that ventricular arrhythmias may be triggered by exercise meant ICD patients were cautiously referred to CR programmes. The safety and benefits of CR including exercise training and testing were analysed by Zecchin et al. (2011) showing that exercise was deemed safe in ICD patients (n=161) with a diagnosis of myocardial infarction or heart failure during a 6 week programme. Also the gain in 'functional capacity' and 'quality of life'

outcomes were significant; exercise testing pre CR 6.9 ±2.2 METS: post CR 9.6 ±2.8 METS $p<0.001$ and 6 minute walk test pre CR 373 ±121 m: post CR 430 ±124 m, $p=0.04$.

1.5.2 Anxiety and depression

After a patient has experienced ICD therapy it has been noted that up to 50% of survivors are known to have significantly higher levels of anxiety, depression, anger and fear in returning to normal physical activities. Few interventions to improve adjustment have been evaluated (Dougherty, Marcus Lewis, Adams, Thompson, Baer, & Kim 2004). Telephone intervention during the first 8 weeks by expert cardiovascular nurses decreased ICD related physical symptoms and anxiety.

Fitchet et al. (2003) stated from their own experience that they have seen ICD patients develop phobic anxiety states, depression and fears of exercise and ICD discharge. This study on a small number of ICD patients (n=16) included four patients with inherited cardiac conditions importantly demonstrating exercise was a safe component of the CR programme with a significant improvement in exercise times ($p=0.001$) and anxiety and depression scores (HADS) improved after the 12 week CR programme ($p<0.001$ and $p=0.002$ respectively) and were maintained 12 weeks after the programme was completed. A 24 hour helpline run by an arrhythmia nurse gave extra support and advice; this is not common place in most implant centres and should be considered as part of the support that these patients require. This is one of very few studies with participants having an inherited cardiac condition diagnosis.

For many individuals an ICD is mostly accepted as a life-saving piece of technology yet many adjustments to life after ICD implantation may vary according to the person's age. McDonough (2009) used qualitative methods to describe the experiences and concerns of

younger adults aged 18-40 years (n=20) living with an ICD. The data revealed that young adults with ICD's have unique concerns of childbearing, childrearing and worry about financial security. This implies that age-appropriate counselling and interventions may be needed before and after ICD implantation.

In a study which included inherited cardiac conditions patients (n=45, mean age 21 years) or those with idiopathic ventricular fibrillation, Wojcicka, Lewandowski, Smolis-Bak, & Szwed (2008) assessed quality of life and psychological problems using a specially designed questionnaire. The main issues examined were whether they had experienced ICD shocks, was behaviour, sleeping or concentration affected and lastly had they any problems with everyday activities including education, work, driving or physical activity. Closed and open questions were used, this gained a greater patient perspective on what advantages and disadvantages of living with an ICD were. The time lapse of 5 months to 11 years of when the ICD was implanted may have influenced the results as over time there is an increase chance of a shock being delivered and risk of infection when an ICD box is changed. Highlighted was the need of information about the device and its functioning and importantly psychological support from health professionals familiar with ICD's. Eventually over half the group decreased the amount of physical activity as they were anxious about receiving further shocks. Without structured support ICD patients can lose confidence and be less motivated in their everyday activities.

The following year Dunbar et al. (2009) investigated a large group of ICD patients (n= 246) randomising them to usual care advice from their clinician, support group or telephone counselling which was delivered by specialist staff, cardiovascular research nurses or mental health clinical nurse specialists. Patients completed self-reporting questionnaires at baseline during hospitalisation and again at 1, 3, 6 and 12 months post implant. The State-Trait Anxiety Inventory (STAI) and Beck Depression Inventory II (BDI-II) were used in this

study; these are validated measurement tools and have been used on cardiac patients previously to assess anxiety and depression (Beck, Steer, & Brown 1996, Dougherty et al. 2004). The interventions classified as psycho-educational decreased anxiety levels and depression scores at 12 months (p=0.03) in the support group or telephone counselling group. Functional status was measured using the Duke Activity Status Inventory DASI (Mark et al. 2008); the results did not represent an improvement in any of the groups. Telephone counselling was recommended as a cost effective and feasible approach to bridge the gap between acute and outpatient care. For patients living a distance from an implant centre outcomes could improve overall if telephone intervention was available.

Prompting further interest into the younger ICD age group females were examined by Vasquez et al. (2008) in a multicentre trial to see whether anxiety increased in relation to shocks, death and body image. Questionnaires were used, the Florida Shock Anxiety Survey FSAS assesses ICD-specific anxiety including the cognitive, behavioural, emotional and social impacts of shock (Kuhl, Dixit, Walker, Conti & Sears 2006), the Multidimensional Fear of Death Scale MFODS (Neimeyer & Moore 1994) and a Body Image Concerns scale Florida Patient Acceptance Survey FPAS (Burns, Serber, Keim & Sears 2005). Three age groups were analysed using qualitative methods, females under the age of 50 were found to be at greater risk of developing psychosocial distress related to these aspects of living with an ICD. The questionnaires had only been validated in the U.S. and data was only collected at one time point. Focusing on giving women specialist advice post implant could help them improve their quality of life.

More recently a Danish study COPE-ICD (Berg et al. 2011) described the experience and meaning of a comprehensive ICD specific rehabilitation programme for a large group of patients (n=196). COPE-ICD involved patients doing exercise training with physiotherapists from 3 months post ICD implant, twice a week for 12 weeks, and having nurse

consultations in person or by telephone once a month for 6 months, then every two months thereafter during a one year period. A control group had medical follow up and a two hour group session, no psycho-educational follow up or exercise training were offered. Qualitative interpretation was performed through interviews on a small group (n=10). Their conclusion showed patients gained insight and developed a physical attention so they continued physical activity through interpreting body signals and then adjusted their exercise behaviour. More individualised care and support is required in the reflection and coping mechanisms needed to deal with living with an ICD.

1.5.3 Summary

The main gaps in the literature reviewed show regular, organised post ICD implant support is not readily accessible to younger ICD patients with a very small number of studies highlighting this population develop different anxieties to their older counterparts. In summary issues surrounding quality of life, anxiety and depression of ICD patients have been investigated in small studies with intervention by specialist staff. The value of ICD patients joining a CR programme is unclear. CR is a structured and monitored process and can allow these patients initial psychological support plus enhance confidence with physical activity in the early stages after device implant; clearly there needs to be a more defined care pathway for this younger age group of ICD patients. This exploratory study therefore examines whether younger ICD patients benefit from attending a CR programme at Imperial College Healthcare NHS Trust.

1.6 Project aim

This quantitative study aims to establish whether the CR programme offered to younger ICD patients helps improve their quality of life and reduces stress and anxiety levels. Secondly the study will explore the quality of life and stress and anxiety levels of ICD

patients who have not attended a CR programme to see how they are coping with everyday life, a comparison will also be made between the two groups (CR group and non-CR group).

1.6.1 Hypotheses

1. Cardiac rehabilitation for younger ICD patients (less than 50 years of age) improves quality of life (H_1).

2. Cardiac rehabilitation for younger ICD patients (less than 50 years of age) reduces anxiety and depression levels (H2).

Null hypotheses

1. Cardiac rehabilitation for younger ICD patients does not improve quality of life (H_0).

2. Cardiac rehabilitation for younger ICD patients does not reduce anxiety and depression levels (H_0).

Supporting the needs of this group of ICD patients at St. Mary's, Hammersmith and Charing Cross Hospitals (Imperial College Healthcare NHS Trust) involves cardiologists with a special interest in inherited conditions, cardiac rehabilitation and electrophysiology, also cardiac rehabilitation nurse specialists, arrhythmia nurse specialists, cardiac physiologists, an exercise physiologist, a dietician and a clinical psychologist. To date there have been relatively small numbers of ICD patients offered to join the hospital or home based exercise programme mainly due to a revision of Cardiology services within the Trust and securing long term funding for the CR programme.

Chapter 2 - Method

2.1 Patients

The sample size for this study was 20 patients with primary prevention ICD implants divided into two independent groups, half (n=10) were randomised from the CR team database and would complete a CR programme (CR group) and half (n=10) were randomised from the inherited cardiac conditions database and would have not completed a CR programme (non-CR group). The mean age of CR group was 37± 6.90 years (range 28-49 years), five were male and five were female. The mean age of the non-CR group was 40.7± 7.90 years (range 23- 50years), seven were male and three were female. Time from ICD implant in CR group was 3± 1.25 months, the time from ICD implant in non-CR group was 12.2± 7.13 months.

Table 1 - Ethnicity

Ethnic background	CR group (n=10)	Non-CR group (n=10)
Caucasian	6	7
Asian	3	2
Black	1	1

2.2 Design

This was an exploratory study using retrospective data collected by the CR team at Charing Cross Hospital between March 2011 and September 2012, and prospective data collected by the researcher through postal questionnaires between September and October 2012. The study design is classified as a 'survey'. Data from two independent group's questionnaires were analysed, the CR group and non-CR group.

2.3 Ethical approval

To conduct this exploratory study NHS ethical approval was granted through the National Research Ethics Service Proportionate Review sub-committee on 22nd August, 2012 (Appendix 1). Following this the Research and Development department at Imperial College Healthcare NHS Trust confirmed approval on 13th September, 2012. Patients who agreed to take part in the study sent a signed and dated consent form back in the stamped addressed envelope with their questionnaires and kept one for their own records.

2.4 Inclusion and exclusion criteria

Inclusion criteria

- Patients who have had an ICD implanted in the last 18 months
- 18 to 50 years of age
- Diagnosis of an inherited cardiac condition (Hypertrophic Cardiomyopathy, Dilated Cardiomyopathy, Arrhythmogenic Right Ventricular Cardiomyopathy, Brugada syndrome, Long QT Syndrome, Catecholaminergic Polymorphic Ventricular Tachycardia)
- Unexplained cardiac arrest

Exclusion criteria

- Under 18 years of age
- Over 50 years of age
- Attended CR programme at another centre
- Previous myocardial infarction

2.5 Procedure

The ICD patients who were enrolled in the CR programme were selected from the cardiac rehabilitation service database within Imperial College Healthcare NHS Trust. Patients who

had not attended a CR programme were selected from an inherited cardiac conditions database within Imperial College Healthcare NHS Trust. All selected patients had an ICD implanted in the last 18 months. Retrospective data was collected from the Dartmouth Co-op quality of life questionnaire (see Appendix 4) completed before and after the CR programme at Charing Cross Hospital (Imperial College Healthcare NHS Trust) as well as scores from a Hospital and Anxiety Depression Scale (HADS) sheet (see Appendix 5) also completed before and after the CR programme. The same quality of life questionnaire and HADS sheet were posted to the patients who did not attend CR to gain a picture of their quality of life with an ICD. An information letter and consent form (Appendix 2 and 3) were included with the questionnaires along with a stamped addressed envelope to return it in. Each questionnaire and score sheet had an identification number to maintain patient anonymity.

An additional question was added to the non-CR group questionnaires to establish if the individual were offered to attend a CR programme would they consider attending. As the questionnaire and score sheet were written in a standardised format all patients were able to answer the questions in the same way therefore portraying more reliable results. To ensure a high response rate from the non-CR group an expected time to complete both sheets was included. A telephone or text message reminder was made two weeks after the questionnaires were initially posted.

2.6 Format of the Cardiac Rehabilitation Programme

Each patient referred to the CR team is initially assessed by the cardiac rehabilitation nurse specialist and exercise physiologist. Baseline blood pressure measurement is recorded along with an activity of daily living and risk factor assessment, in addition a quality of life questionnaire and HADS sheet are usually completed at this point; on occasion patients have been noted to refuse to complete the questionnaire when asked. During the exercise

component of the programme the patient performs the shuttle walk test, Chester step test or 6 minute walk test as appropriate. Alternatively patients are offered a home based programme prescribed by the exercise physiologist which can be a home circuit programme, exercise DVD, walking programme, chair based or support-standing option; this is often tailored to their specific needs. They are then asked to return for an end of programme assessment after 8 weeks. There is opportunity to see a dietician after the initial assessment and referral to a clinical psychologist with experience of cardiac patients can be made if appropriate, input from the psychologist may continue beyond the 8 weeks if necessary.

2.7 Questionnaires

The Dartmouth Co-op quality of life questionnaire and Hospital Anxiety and Depression score sheet are reliable and well validated (Zigmond & Snaith 1983). There are nine sections in the quality of life questionnaire; physical fitness, feelings, daily activities, social activities, pain, change in health, overall health, social support and quality of life, a score of between 1 to 5 is selected by the respondent. A score of 4 or 5 means the patient may need intervention to help them. It has been found that if patients complete the questionnaire and many scores are ‘3’, they are called the educated 'fence riders' that are not quite ready to admit they are having trouble in the functional areas.

The Hospital Anxiety and Depression scale (HADs) consists of 14 statements where one tick box is selected out of four choices of how the person is feeling. The scores are not visible to the respondent however the scoring system for each statement chosen is between 0 and 3 for either anxiety or depression; a total score of 8 or more for either is classified as a problem and intervention may be needed.

All questionnaire scores were entered into a Microsoft Excel spreadsheet against the identification numbers assigned to each patient. Additional information was entered on the

type of ICD implanted (single/ dual lead or sub-cutaneous) and also how many visits were made by patients referred to the clinical psychologist. An additional question was asked to the non-CR group regarding whether they would consider attending a CR programme, a summary of the responses to this will be presented in the discussion.

2.7 Data analysis

The quality of life questions and HADS statement scores produced ordinal data; firstly this was explored using descriptive statistics and inferential statistics. Graphs were also produced in Microsoft Excel 2010 to show differences and trends in individual patients' scores for all components of the quality of life questionnaire and the anxiety and depression scores. Due to small numbers recruited a non-parametric approach using a Wilcoxon signed rank test compared pre and post CR group questionnaire scores and a Mann Whitney U test was used for analysis of both groups' questionnaire scores. SPSS statistical package (version 20.0) produced statistical data (see Appendix 6 and 7). A level of significance was assessed at $p<0.05$.

Chapter 3 - Results

A total of 10 quality of life questionnaires and 10 HADS score sheets were posted to ten ICD patients who had not attended cardiac rehabilitation.

Table 2 - Variation in diagnoses

Diagnosis	CR group (n=10)	Non-CR group (n=10)
Hypertrophic Cardiomyopathy (HCM)	3	7
Dilated Cardiomyopathy (DCM)	1	0
Brugada syndrome	2	2
Long QT Syndrome (LQTS)	2	0
Catecholaminergic Ventricular Tachycardia (CPVT)	1	0
Arrhythmic Right Ventricular Cardiomyopathy (ARVC)	0	0
VF arrest	1	0
Myotonic dystrophy	0	1

3.1 Adherence to Cardiac Rehabilitation attendance

The number of patients completing the eight week CR programme successfully at Charing Cross Hospital was five. Mean age was 33.4 ±4.62 years (age range 28-39). The other five patients did not complete the programme for various reasons. One did not attend a final assessment appointment. Another attended an initial assessment and then did not attend further exercise classes or appointments with the clinical psychologist; eventually they rebooked to see the clinical psychologist. A third patient started the CR programme late after changing an initial assessment appointment several times and then did not attend further appointments. Lastly, two others had their ICD implant delayed, one by the hospital and one because of travel abroad, therefore they started the CR programme later than anticipated and did not complete the programme within the study timescale. Pre CR

programme quality of life and HADS scores were recorded by the cardiac rehabilitation team for nine out of ten patients and the post CR questionnaire scores were only available for five out of ten. In the non-CR group eight out of ten patients returned the questionnaires by post; none had attended other CR programmes.

3.2 Summary of results – Quality of Life

The median and range of each quality of life questionnaire component are summarised in Table 3.

The change in pre and post CR scores are represented in percentage (%) and a non-parametric Wilcoxon signed rank test was used to give p values (significance <0.05) as these scores are within the same group, the CR group.

Table 3 - Summary of results for all quality of life questionnaire components before and after eight weeks of cardiac rehabilitation (n=5)

QoL component	Pre CR Median Range	Post CR Median Range	% change in score	p value
Quality of life	2.50 2	2.00 2	-12.5	p=0.180
Social activities	2.00 4	2.00 3	0	p=0.180
Daily activities	3.00 4	2.00 3	-25	p=0.157
Social support	2.00 4	2.00 2	0	p=0.564
Physical fitness	3.00 3	2.00 3	-25	p=0.317
Feelings	2.00 4	2.00 3	0	p=0.317
Pain	2.00 2	3.00 2	25	p=1.000
Change in health	3.00 1	3.00 1	0	p=0.317
Overall health	3.00 4	3.00 3	0	p=0.157

Patients who completed the CR programme (n=5) showed an improvement in scores for quality of life, daily activities and physical fitness. The differences in scores in these three

components however were not significantly different as p>0.05. None of the other components pre and post CR scores showed any signifcant differences. In social activites, social support, feelings, change in health and overall health there was no change in the median scores before and after the CR programme.

A representation of each respondents pre and post CR scores in the nine categories are shown in the following graphs illustrating changes.

Quality of Life

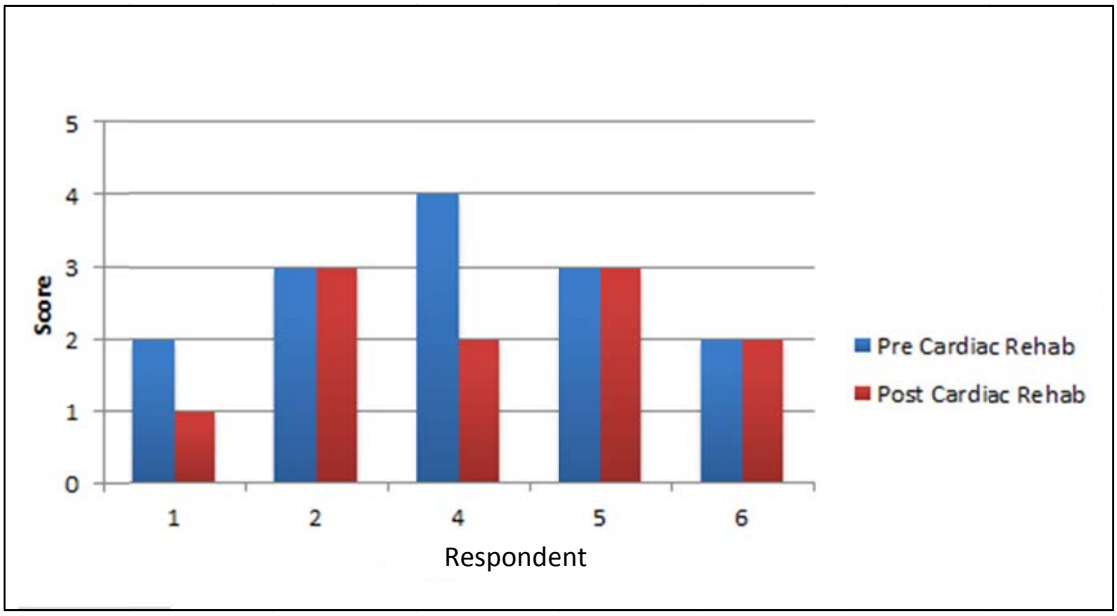

Figure 1- Results for 'quality of life' component for pre and post eight weeks of cardiac rehabilitation

Quality of everyday life improved for two out of five patients following the CR programme. One of the patients scored '4' which is deemed to highlight a problem, their quality of life was 'pretty bad'which then improved by two points to 'pretty good' after completing the CR programme. In total three out of five patients had no difference in their scores pre and post CR.

Social Activities

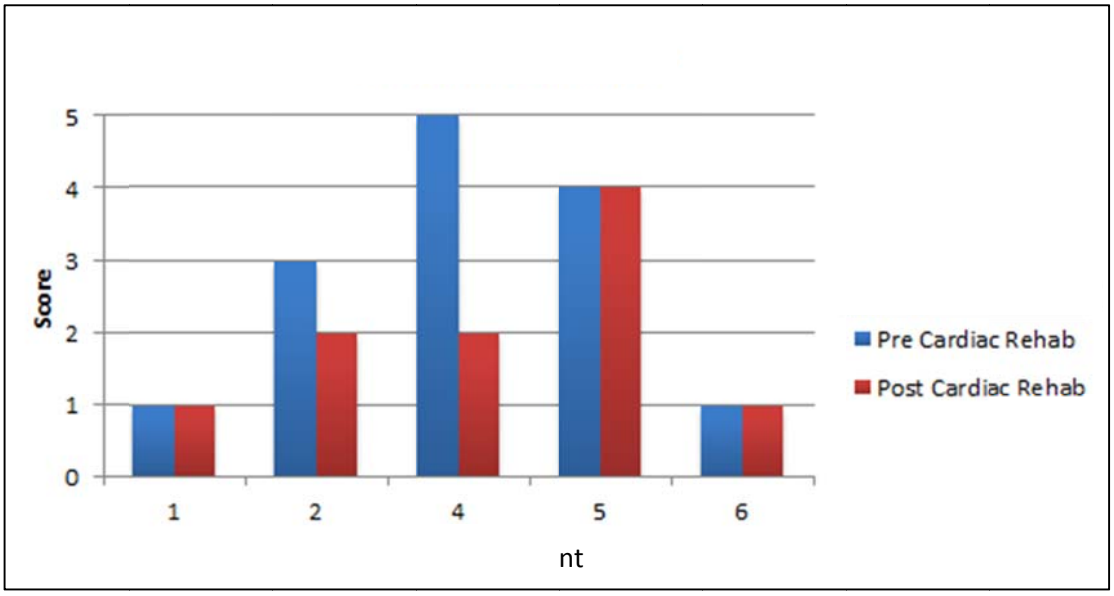

Figure 2 - Results for social activities component for pre and post eight weeks of cardiac rehabilitation

Responses to physical and emotional health limiting social activity with family, friends, neighbours or groups showed improvement for two out of five of patients. One patient reported their health limited social activities 'extremely' (score of 5) which after the CR programme was only 'slightly' (score of 2).There was no change for three out of five patients.

Daily Activities

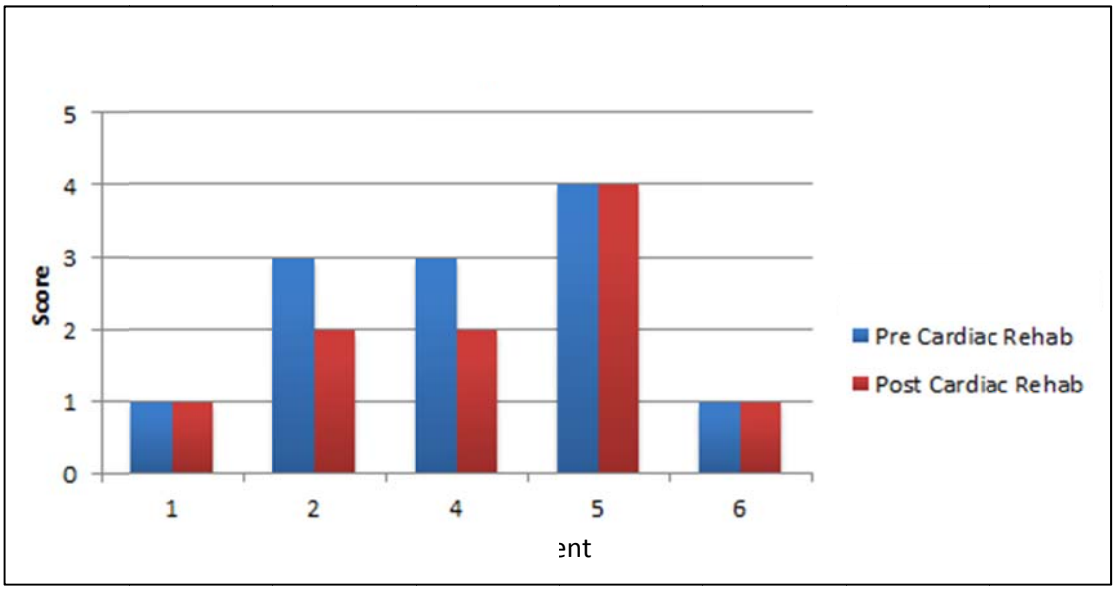

Figure 3 - Results for daily activities component for pre and post eight weeks of cardiac rehabilitation

There was improvement in the performance of daily activity for two out of five patients, from experiencing 'some difficulty' to 'little difficulty' because of physical and emotional health; this question relates to doing usual tasks inside or outside the house. There was no change in three out of five of the patients.

Social Support

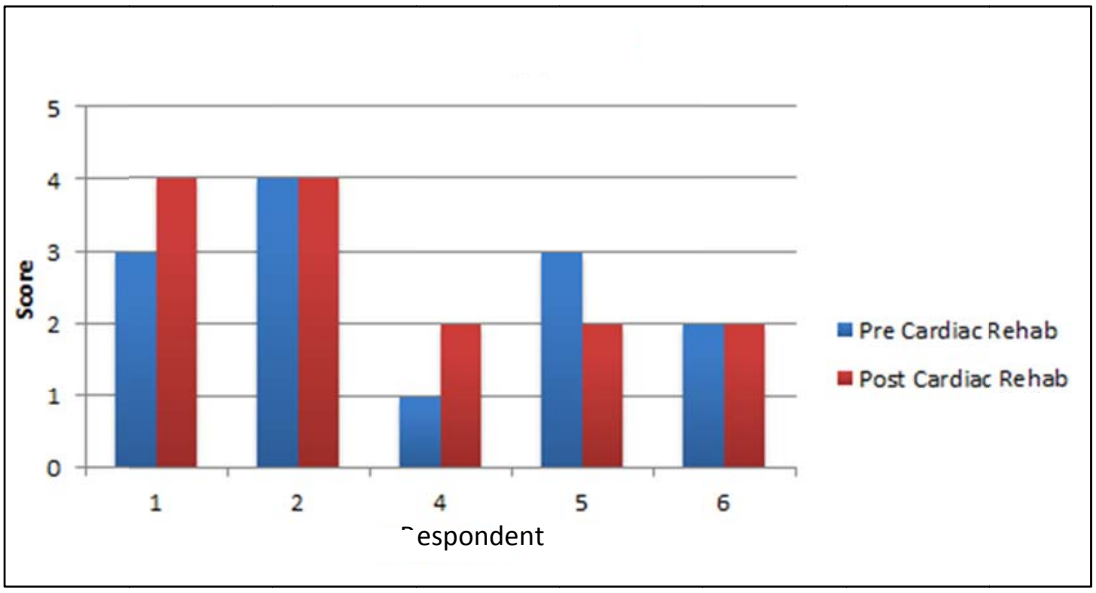

Figure 4 - Results for social support component pre and post eight weeks of cardiac rehabilitation.

When asked if someone was available to help if they needed help ie. with daily chores, taking care of themselves, if they got sick or needed someone to talk to one out of five patients showed an improved score from 'some' to 'quite a bit' of help. There were two out of five patients who reported less social support after the eight weeks and had an increase of one in their scores.

Physical Fitness

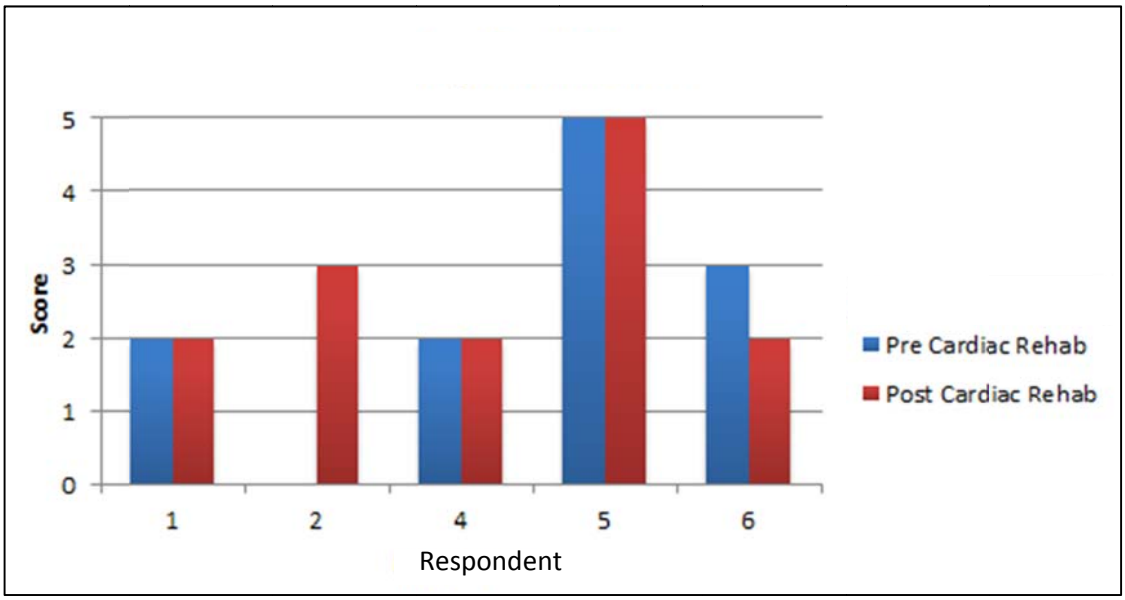

Figure 5 - Results for physical fitness component for pre and post eight weeks of cardiac rehabilitation

One patient showed improvement in their physical fitness score following the CR programme, from being able to perform 'moderate' physical activity (walking at medium pace) for at least two minutes to performing 'heavy' physical activity (jog at slow pace, climb stairs or hill at moderate pace); this was a change of one score. There was no change for two out of five patients, they were performing 'moderate' physical activity before the CR programme. One patient continued to do 'very light' physical activity inspite of completing the programme.

Feelings

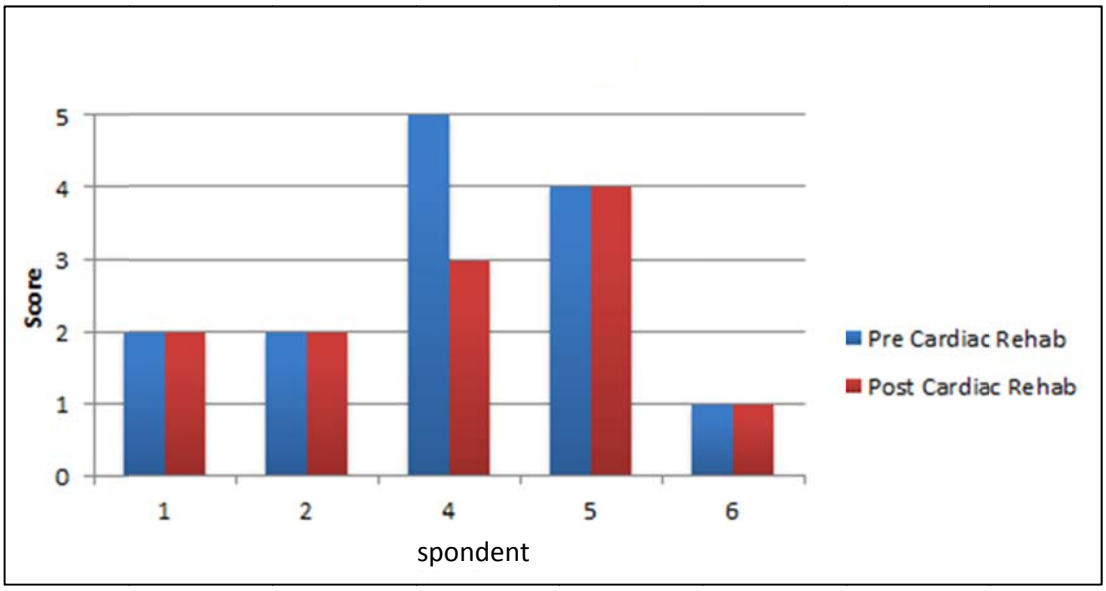

Figure 6 - Results for feelings component for pre and post eight weeks of cardiac rehabilitation

In this component two out of five patients scored 4 or 5 highlighting a problem with emotional problems ie. feeling anxious, depressed, irritiable, downhearted or blue. These two patients were seen by the clinical psychologist with one patient showing an improvent in this area scoring 3 (moderately bothered by emotional problems) after completing the programme; in total the patient was seen by the clinical psychologist fifteen times. The other patient has continued to be reviewed by the psychologist.

Pain

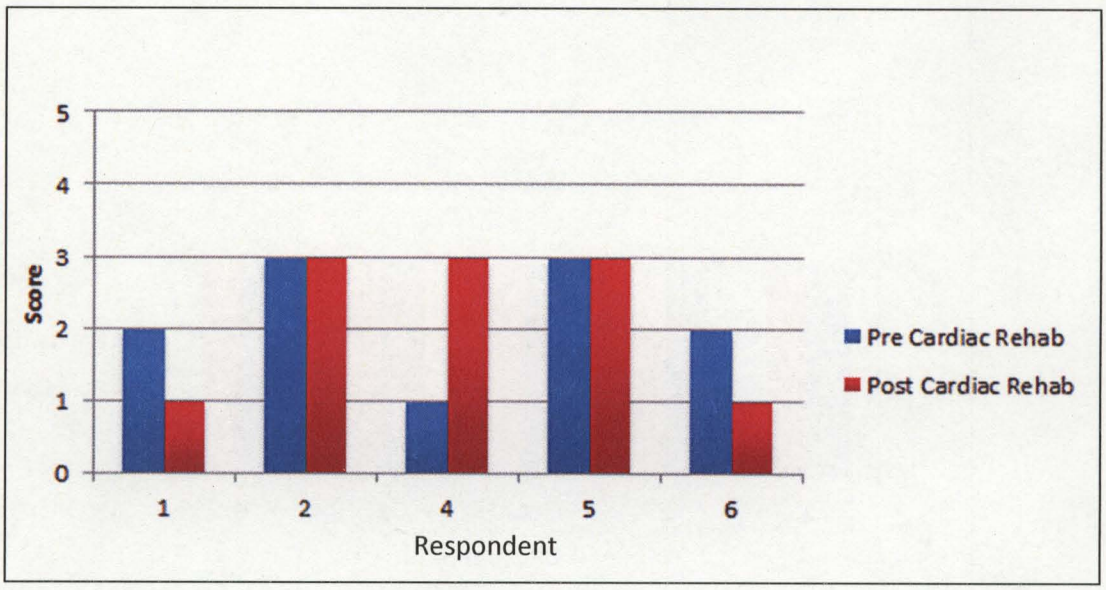

Figure 7 - Results for pain component for pre and post eight weeks of cardiac rehabilitation

The pain component refers to how much bodily pain has the patient had during the last week. An improvement in pain was reported by two out of five patients. A further two out of five patients had no change and one patient had a slight increase from 'no pain' to 'mild pain'. No respondents scored 4 or 5, 'mild pain' was therefore the highest level reported.

Change in Health

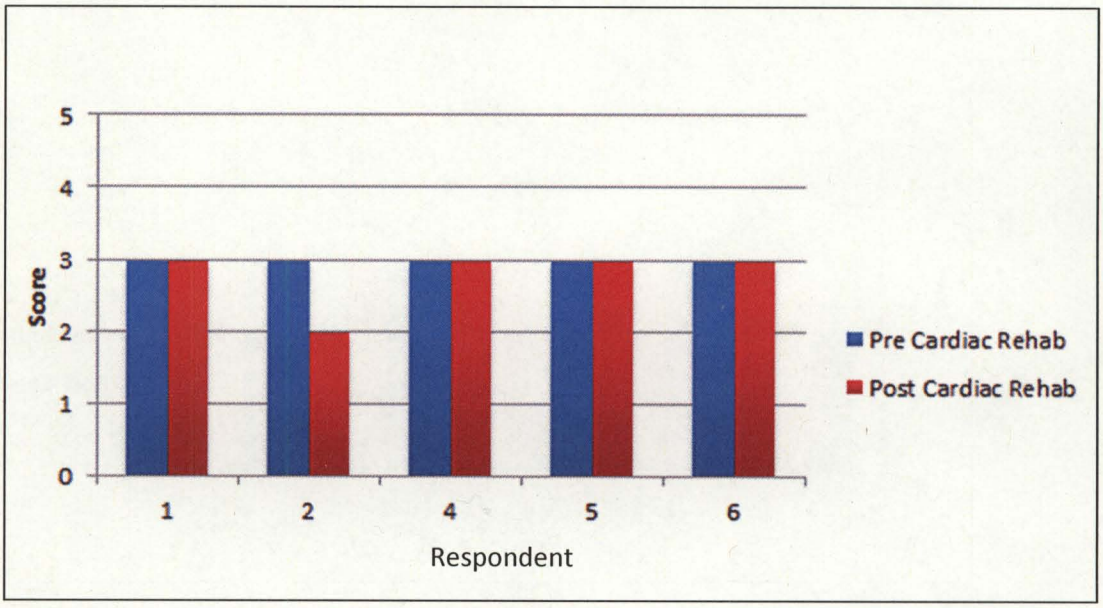

Figure 8 - Results for change in health for pre and post eight weeks of cardiac rehabilitation

These scores represent how patients' perceive their overall health compared to a week ago; one out of five patients reported a slight improvement from 'about the same' to ' a little better'. Four out of five patients reported no change with a score of 3 meaning 'about the same'. This comparison in pre and post scores did not show any significant differences in health status over a short period.

Overall Health

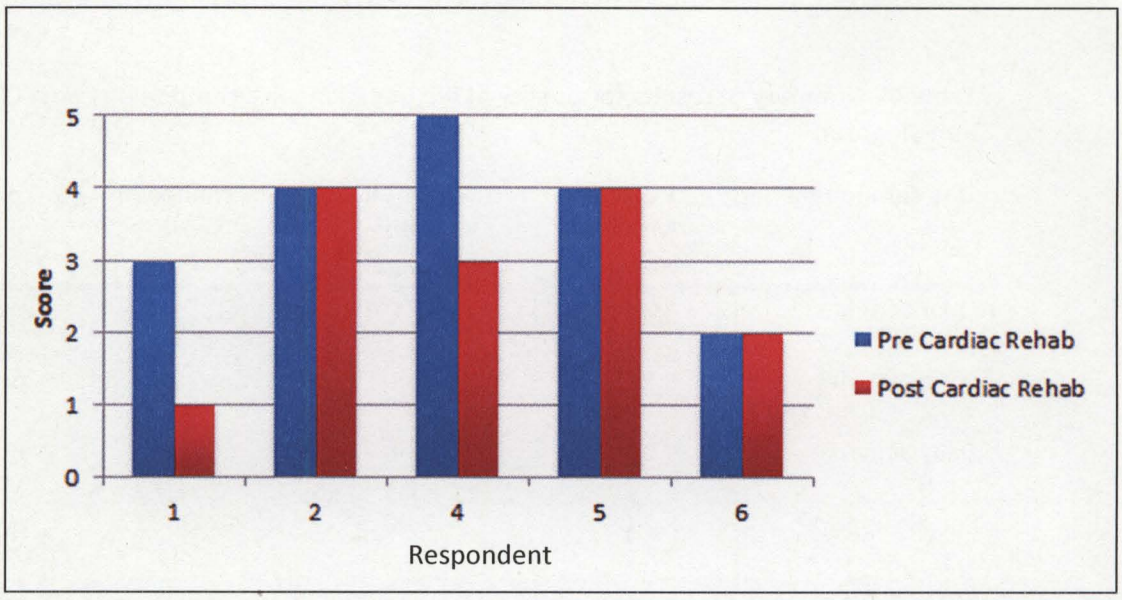

Figure 9 - Results of overall health for pre and post eight weeks of cardiac rehabilitation

General health in the past week improved for two out of five patients with three out of five patients showing no difference in their post CR scores. Looking at higher scores three out of five patients scored a 4 or 5 meaning they perceived their health as 'fair' or 'poor' pre CR. Two of these patients were seen by the clinical psychologist.

A Mann Whitney U test was performed to look at significant score change between the CR group's post CR quality of life scores and the non CR group's quality of life scores.

Table 4 - Summary of results for quality of life questionnaire components post CR and non CR group

QoL component	Post CR Median Range	Non-CR Median Range	% change in score	p value
Quality of life	2.00 2	2.00 1	0	p=0.718
Social activities	2.00 3	1.00 1	-25	p=0.274
Daily activities	2.00 3	2.00 2	0	p=0.754
Social support	2.00 2	2.00 4	0	p=0.367
Physical fitness	2.00 3	2.50 1	12.5	p=1.000
Feelings	2.00 3	2.00 3	0	p=0.695
Pain	3.00 2	2.00 3	-25	p=0.820
Change in health	3.00 1	3.00 0	0	p=0.206
Overall health	3.00 3	3.00 1	0	p=0.638

Overall ICD patients who had not attended a CR programme (n=8) had lower scores for social activities and pain components than those who had completed the programme; these results did not show a significant difference in scores $p>0.05$.

3.3 Summary of results - Hospital Anxiety and Depression Scale

Summary of anxiety and depression scores from the CR group HADS score sheet, minimum score = 0, maximum score =21. A score of greater than 8 may need intervention.

Table 5 - Results for anxiety and depression for pre and post eight weeks of cardiac rehabilitation

	Pre CR Median Range	Post CR Median Range	% change in score	p value
Anxiety	7.00 12	8.00 11	4.76	p=0.680
Depression	9.00 14	6.00 12	-14.29	p=0.06

There was a 4.76% increase in the pre and post anxiety scores, no significant difference in scores was found, p> 0.05. The depression scores improved following the CR programme, pre and post depression scores reduced by 14.29%, however this was not found to be a significant change (p=0.06).

Anxiety

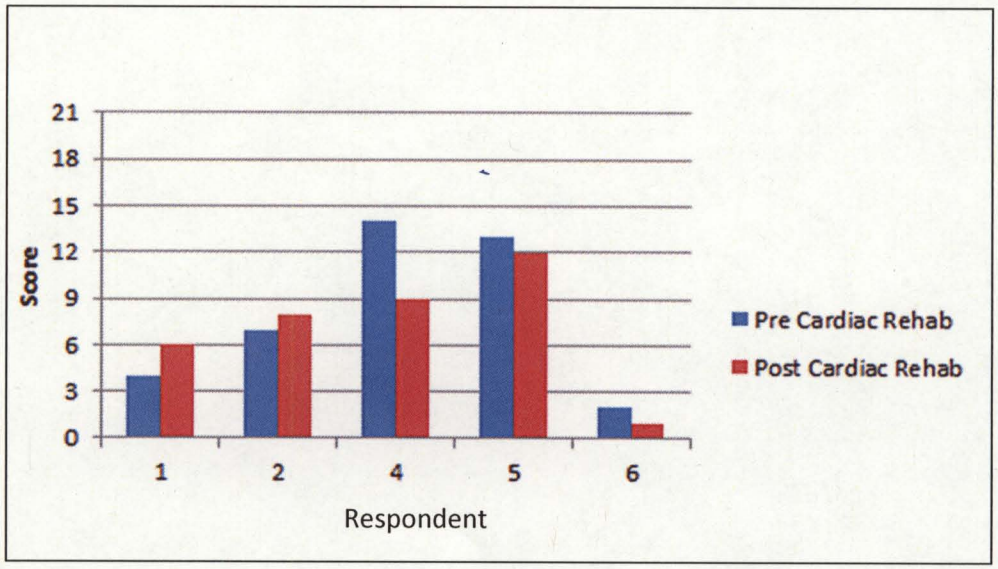

Figure 10 - Results for anxiety for pre and post eight weeks of cardiac rehabilitation

Scores of greater than 8 represented a problem of anxiety in two out of five patients at their initial assessment. Those encountering difficulties scored high in areas such as 'feeling tense', 'frightened feeling, something awful might happen', 'worrying thoughts', 'not able to sit at ease and relax', 'feeling restless', and 'sudden feelings of panic'. Overall there was an improvement in anxiety scores for three out of five patients however two out of five patients had a slight increase in their scores. Areas where post CR scores were higher included

Depression

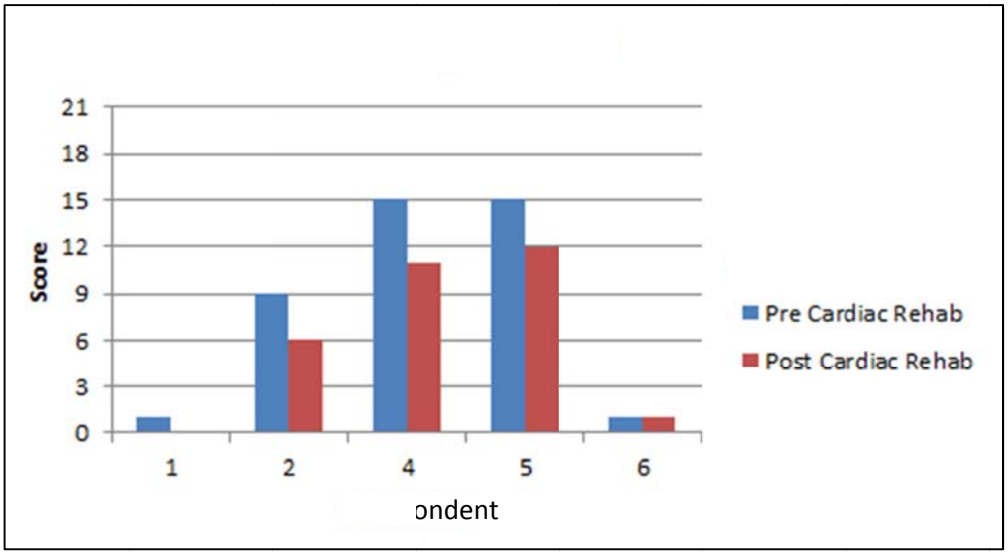

Figure 11 - Results for depression for pre and post eight weeks of cardiac rehabilitation

There were significant high scores of greater than 8 in three out of five of the patients at their initial assessment. Higher scores were seen in areas relating to 'less enjoyment in things enjoyed previously', 'less able to see the funny side of things', 'less cheerful', 'feeling slowed down', 'losing interest in appearance', ' not looking forward to things', 'not able to enjoy a good book, radio or TV programme.' Both patients who scored 15 on the HADS sheet saw the clinical psychologist a total of 15 times. Of the three out of five patients whose scores represented a problem with depression, all of them had a lower score following completion of the programme. Four out of five patients had an overall improvement in their post CR HADS scores.

Table 6 - Results of anxiety and depression scores post cardiac rehabilitation and non-cardiac rehabilitation group

	Post CR Median Range	Non-CR Median Range	% change in score	p value
Anxiety	8.00 11	5.50 11	-11.9	p=0.556
Depression	6.00 12	2.00 8	-19.05	p=0.337

These results show that overall the non-CR group had lower scores for anxiety and depression than the CR group who had completed the CR programme. Differences in scores between the two groups was not significant following a Mann Whitney U test, $p>0.05$.

Chapter 4 – Discussion

This study explored younger ICD patients who were referred to an existing eight week CR service. An evaluation of quality of life, anxiety and depression was made; four patients in the CR group chose a home based exercise programme over a hospital one. The inclusion age criteria for this project was 18 to 50 years and was chosen as there are increasing numbers of primary prevention ICD implants in younger patients at risk of ventricular arrhythmias. The main objective was to identify if the programme was beneficial to this younger group of inherited cardiac condition ICD patients (CR group) and furthermore explore the quality of life of similar ICD patients who had not yet accessed a CR programme (non-CR group). Five out of ten ICD patients completed a quality of life questionnaire and HADS sheet before and after the eight week programme. Eight patients who had not attended a programme returned the same questionnaires, and in total three patients did not complete the programme within the study timescale. Scores for each of the nine quality of life components were analysed as a repeated measure design pre and post CR (CR group), secondly a comparison was made between the two groups scores, post CR group scores and non-CR group scores using non-parametric tests (Mann Whitney U test). The components were physical fitness, feelings, daily activities, social activities, pain, change in health, overall health, social support and quality of life. In addition scores from the HADS sheet for anxiety and depression were analysed using the same method.

4.1 Cardiac rehabilitation programmes

As CR has proven to benefit cardiovascular patients in gaining confidence and motivation to continue with daily activities and promote physical fitness it seems important that ICD patients of any age should be offered structured support through specialist cardiology teams after their ICD implant. The current CR service at Imperial College Healthcare NHS Trust is able to offer ICD patients the opportunity to improve their quality of life yet may need to be tailored to meet specific needs of the younger age group. Due to busy lifestyles,

long working hours and family commitments younger patients have difficulty finding time to attend appointments on a regular basis thus potentially explaining why few patients may not be completing the programme successfully. Drop-out rates in other cardiac rehabilitation programmes reported a drop-out rate of just below 50% in a group of cardiovascular disease patients (Worcester, Murphy, Mee, Roberts, & Goble 2004). Attendance rates were also low at 7.2% in the study by Dunbar et al. (2009). In this study two patients joined the programme later than anticipated due to non-medical reasons (hospital cancellation and travel abroad) therefore highlighting a limitation of the study's timescale to analyse their end of programme questionnaire data. Therefore the drop-out rate was three out of ten before the end of the eight week programme.

The recent study from Berg et al. (2011) where a comprehensive CR programme was developed solely for ICD patients has supported the notion for specific ICD patient follow up; the final results have not yet been published. In context this younger age group may positively view a less traditional approach of cardiac rehabilitation (weekly appointments) and instead favour an extended time frame of follow up ie. more than eight weeks and longer less frequent sessions could improve attendance rates. This would not be cost-effective in the long term as specialist cardiology staff would need to make regular telephone calls or increase the number of clinic reviews.

4.2 Quality of Life

The main objective was to explore if quality of life questionnaire scores reduced after completion of an eight week CR programme. A Wilcoxon signed rank test showed no significant difference in pre and post CR quality of life scores ($p>0.05$) however the responses did show a percentage change improvement of scores for 'quality of life' (12.5%), 'daily activities (25%)' and 'physical fitness' (25%) at the end of the programme (see Table.3). Therefore the null hypothesis could not be rejected. From a quality of life

perspective the CR group did not show significant differences overall in quality of life scores which is similar to the summary from Thomas et al. (2006) where ICD patients under 50 years of age were at risk of poor quality of life post implant. Results from Dubin, Batsford, Lewis, & Rosenfeld (1996) on the contrary showed young ICD patients reported 'good' to 'excellent' rating of health and were all able to perform activities of daily living which correlates with improvements found in this study. The mean time from ICD implant was much longer in their study (3.3 years).

Reflecting on individual cases, respondent no.4 showed the largest decrease in scores for 'quality of life', 'social activities', 'feelings' and 'overall health' components. An increase in 'social support' post CR scores for three of the patients somewhat compares to the issue raised of perceived social support over the first year in Kamphuis et al. (2004) study. Therefore it may reasonable to emphasise that CR did help certain individuals improve their quality of life to a degree however more longitudinal data is required to establish if quality of life improvement is maintained. One explanation for patients' scores not improving in certain components could relate to on-going psychological support for anxiety or depression which may hinder their recovery in the short term. Due to small numbers completing the programme there is an unclear representation of how younger ICD patients recover in general and findings should be interpreted with caution. It may be prudent to monitor this younger age group in conjunction with other specialist implant centres as the number of ICD implants for this inherited cardiac conditions group is not.

On review of the Dartmouth Co-op quality of life questions a number refer to change in health or emotion 'within the last week', the patients' response does not reflect how aspects of everyday life have changed over many weeks. A number of studies have used the Medical Outcomes Study SF-36 (short form survey instrument 36-item) which has questions referring to the 'last 4 weeks' and general health 'a year ago'. This questionnaire

gives a broader perspective and may be more appropriate to use with this group of ICD patients.

The comparison of the CR group (post CR scores) and non-CR group quality of life scores also showed limitations due to the fact the non-CR group time from implant was much longer than the CR group (mean time from implant CR =3 months, non-CR =12.2 months). Patients' who had their ICD implanted more than a few months ago have had time to settle into life with a device, return to employment and regular physical activity. One-time questionnaire scores from the non-CR group proved to be another limitation in this study as a repeated measure comparison of pre and post data of both groups could not be performed.

4.3 Anxiety

The HADS sheet is usually completed at the initial assessment of the cardiac rehabilitation programme, and if the patient scores more than 8 for anxiety or depression a review by the clinical psychologist is discussed and a referral made if agreed by the patient. In this study the HADS scores were analysed using a Wilcoxon signed rank test and showed no significant difference in the pre or post anxiety scores for the CR group ($p=0.680$), there was a small increase in post CR anxiety scores for respondents 1 and 2 (see figure. 10), these patients did not score more than 8 at baseline. These increases were related to 'social support' for respondent 1 and 'overall health' and 'social support' for respondent 2. This may indicate that continued support from family and friends is important in the long-term and not just during the initial recovery period. Two respondents who were followed up by the clinical psychologist did have a decrease in their anxiety scores and were reviewed after the eight weeks.

When the CR group (post CR scores) and non-CR group scores were compared the median scores were lower for the non-CR group however a Wilcoxon signed rank test was used

which showed no significant difference between the two groups anxiety scores (p=0.556). As highlighted before the non-CR group had their ICD implant for longer therefore issues with anxiety could have been addressed in the early recovery months. Personal tragedy such as sudden death in the family could contribute to a higher anxiety score rather than an ICD related anxiety score. This in turn is a reminder of individual cases, personalities and social circumstances which make a general CR programme perhaps not suitable for everyone.

4.4 Depression

Scores for depression showed an improvement for patients who scored more than 8 at baseline. A Wilcoxon signed rank test did not show a significant difference in the pre and post depression scores for the CR group (p= 0.06). Two respondents who scored 15 out of 21 at baseline had an improvement in their post CR scores and as mentioned previously continued to be reviewed by the clinical psychologist after the eight weeks. These changes are similar to findings by Dunbar et al. (2009) where depression improved over the first 12 months.

4.5 Comments from non-CR group

An additional question was added on the questionnaire to the non-CR group as to whether they would consider attending a CR programme; this was because the current service did not have all the specialist staff in place in the last two years and some patients had not been referred to CR after their ICD implant. Overall there were mixed responses, some patients felt a programme would have been beneficial to attend in the early months after having their ICD but not now as many months had passed and they were used to living with the device. Two females and two males were interested in being referred to the CR programme. One patient felt the ICD had relieved ‘worry’ about collapse but would still like to improve his quality of life. Another patient said the recovery post implant was ‘long’ and

was unsure if some anxieties were due to the sudden death of a relative the previous year rather than because of having an ICD.

4.6 ICD specific Cardiac Rehabilitation

This concept has only recently been investigated in a large group by Berg et al. (2011) and the results of their study will impact on rehabilitation practice and future support of ICD patients. At Imperial College NHS Trust there would only be evidence of the benefits of CR for ICD patients once more have gone through the programme and if data is collected and reviewed at specific time points. Formal follow up would be required beyond the end of CR to capture quality of life information, either through telephone contact or out-patient clinics. In the current economic climate NHS healthcare is under pressure to reduce costs which in turn could impact on these services which are important to a growing number of patients. In addition the type of quality of life questionnaire currently used (Dartmouth Co-op) needs review as there may be a more appropriate data collection tool to gain a broader perspective of life with an ICD. Improving processes to increase patient interest in uptake and completion of a CR programme along with ICD specific care pathways would ensure appropriate referrals. The patients' underlying cardiac condition and experience of collapse may influence the timing of when best to start CR.

4.7 Conclusion

The initial hypothesis made as to whether CR can improve younger ICD patients' quality of life is not accepted as there were too few patients who successfully completed the programme. Improvements seen in quality of life component scores should be noted even though statistically the differences were not deemed to be significant. A larger scale study with other specialist implant centres in the UK could provide a wider picture of how quality of life truly is for this younger age group. Anxieties surrounding an inherited cardiac condition diagnosis and in addition family members who may also be affected can add

further problems in dealing with the impact of having an ICD. This exploratory study provided a valuable insight into the current recovery of younger ICD patients who are followed up by Imperial College NHS Trust. Results discussed cannot be generalised to a wider ICD population yet can enhance what little information there is on this younger age group's quality of life.

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Appendix 1 – Ethical Approval

NHS
Health Research Authority

National Research Ethics Service

NRES Committee London - Fulham
HRA NRES Centre Manchester
Barlow House
3rd Floor, 4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7821
Facsimile: 0161 625 7299

Dear Mrs Grieger

Study title:	An exploratory study to determine if younger patients' with implantable cardioverter defibrillators have an improved quality of life following cardiac rehabilitation.
IRAS Project Number	106850
REC reference:	12/LO/1448

The Proportionate Review Sub-committee of the NRES Committee London - Fulham reviewed the above application on 20 August 2012.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation.

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Evidence of insurance or indemnity		09 July 2012
Investigator CV	Dr Stephen Fallows	10 August 2012
Investigator CV	Andrea Greiger	08 August 2012
Letter from Sponsor	University of Chester	13 August 2012
Letter from Statistician		10 August 2012
Participant Consent Form	2.0	15 August 2012
Participant Information Sheet	1.0	09 August 2012
Protocol	1.0	09 August 2012
Questionnaire: Quality of Life Questionnaire	Validated	
Questionnaire: HADS	Validated	
REC application	3.4	10 August 2012
Summary/Synopsis	1.0	09 August 2012

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

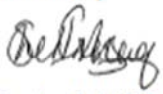
You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

12/LO/1448	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely



Signed on behalf of:
Dr Frank Miskelly
Chairman (Vice-Chair, Chaired the meeting)

Email: shehnaz.ishaq@northwest.nhs.uk

Enclosures:	List of names and professions of members who took part in the review
	"After ethical review – guidance for researchers"
Copy to:	Lucy Parker, Imperial College London and Imperial College Healthcare NHS Trust
	Dr Stephen Fallows – R&D University of Chester
	Sarah Andrew – R&D Department, University of Chester

NRES Committee London - Fulham

Attendance at PRS Sub-Committee of the REC meeting on 20 August 2012

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Marian Cohen	Retired Lawyer	Yes	
Dr Frank Miskelly – Chaired the meeting	Physician (Vice-Chairman)	Yes	
Mrs Gillian Silchau	Occupational Therapist	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Catherine Blewett	Acting Co-ordinator (Centre Manager - HRA NRES Centre North West)

Appendix 2 – Consent Form

Title of Project:
An exploratory study of younger ICD patients' quality of life.

Name of Researcher: Andrea Grieger

Please initial box

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my legal rights being affected. ☐
3. I understand that relevant data collected during the study may be looked at by individuals from the University of Chester, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. I agree to take part in the above study. ☐

Name of Participant	Date	Signature

Researcher	Date	Signature

1 for participant; 1 for researcher

Please return both questionnaires in the stamped addressed envelope provided as soon as possible, thank you.

Appendix 3 – Participant Information Sheet

Participant information sheet

An exploratory study of younger implantable cardioverter defibrillator patients' quality of life.

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

What is the purpose of the study?
The purpose of this project is to examine quality of life and anxiety levels of younger ICD patients who have not attended a cardiac rehabilitation programme and compare this to individuals who have attended a programme.

Why have I been chosen?
You have been chosen as you are between 18 and 50 years of age and have a diagnosis of an inherited cardiac condition, also you have not attended cardiac rehabilitation.

Do I have to take part?
It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect you in any way.

What will happen to me if I take part?
You will need to complete a quality of life questionnaire and anxiety score sheet which will take approximately 20 – 30 minutes in total. Please return them in the stamped addressed envelope provided. It is important to choose a quiet time to complete the questionnaires when you will not have any interruptions. No-one will be identifiable in the final report.

What are the possible disadvantages and risks of taking part?
There are no disadvantages or risks foreseen in taking part in the study.

What are the possible benefits of taking part?
In the future there may be more cardiac rehabilitation programmes developed for younger ICD patients.

What if something goes wrong?
If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study, please contact Professor Sarah Andrew, Dean of the Faculty of Applied Sciences, University of Chester, Parkgate Road, Chester, CH1 4BJ, 01244 513055.

Will my taking part in the study be kept confidential?
All information which is collected about you during the course of the research will be kept strictly confidential so that only the researcher carrying out the research will have access to such information.

What will happen to the results of the research study?
The results will be written up into a dissertation for my final project of my MSc. Individuals who participate will not be identified in any subsequent report or publication.

Who is organising the research?
The research is conducted as part of a MSc in Cardiovascular Rehabilitation within the Department of Clinical Sciences at the University of Chester. The study is organised with supervision from the department, by Andrea Grieger, an MSc student/ Arrhythmia Nurse Specialist based at St. Mary's Hospital, London.

Who may I contact for further information?
If you would like more information about the research before you decide whether or not you would be willing to take part, please contact:

Andrea Grieger –

Thank you for your interest in this research.

Appendix 4 – Quality of Life Questionnaire

QUALITY OF LIFE QUESTIONNAIRE

PHYSICAL FITNESS. During the past week what was the hardest physical activity you could do for at least 2 minutes? **(Place a tick in the box next to the one you feel best describes your fitness)**

Very heavy, for example: run at a fast pace or carry a heavy load upstairs or uphill (25 lbs / 10 kgs)		1
Heavy: for example: jog, slow pace or climb stairs or a hill at moderate pace		2
Moderate: for example: walk at medium pace or carry a heavy load on level ground (25 lbs / 10 kgs)		3
Light: for example: walk, medium pace or carry a light load on level ground (10 lbs / 5 kgs)		4
Very light: for example: walk at a slow pace, wash dishes		5

FEELINGS. During the past week how much have you been bothered by emotional problems such as feeling anxious, depressed, irritable or downhearted and blue? **(Place a tick in the box next to the one you feel best describes your feelings)**

Not at all		1
Slightly		2
Moderately		3
Quite a bit		4
Extremely		5

DAILY ACTIVITIES. During the past week how much difficulty have you had doing your usual activities or task, both inside and outside the house because of your physical and emotional health

No difficulty at all		1
A little bit of difficulty		2
Some difficulty		3
Much difficulty		4
Could not do		5

SOCIAL ACTIVITIES. During the past week has your physical and emotional health limited your social activities with family, friends, neighbours or groups?

Not at all		1
Slightly		2
Moderately		3
Quite a bit		4
Extremely		5

PAIN. During the past week how much bodily pain have you generally had?

No pain		1
Very mild pain		2
Mild pain		3
Moderate pain		4
Severe pain		5

CHANGE IN HEALTH. How would you rate your overall health now compared to a week ago

Much Better		1
A little better		2
About the same		3
A little worse		4
Much worse		5

OVERALL HEALTH. During the past week how would you rate your health in general?

Excellent		1
Very Good		2
Good		3
Fair		4
Poor		5

SOCIAL SUPPORT. During the past week was someone available to help you if you needed and wanted help? For example:

- if you felt nervous, lonely, or blue,
- got sick and had to stay in bed,
- needed someone to talk to,
- needed help with daily chores,
- needed help with taking care of yourself

Yes, as much as I wanted		1
Yes, quite a bit		2
Yes, some		3
Yes, a little		4
No, not at all		5

QUALITY OF LIFE. How have things been going for you during the past week?

Very well: could hardly be better		1
Pretty good		2
Good & bad parts about equal		3
Pretty bad		4
Very bad: could hardly be worse		5

Additional question:

Our cardiac rehabilitation service for ICD patients is still fairly new, if you were offered to attend a cardiac rehabilitation programme would you be keen?

Appendix 5 – Hospital Anxiety and Depression Scale

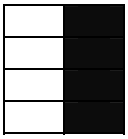
Healthcare professionals are aware that emotions play an important part in most illnesses. If they know about these feelings it will be easier to help you with them. This questionnaire is designed to help healthcare professionals to know how you feel.

Read each item and place a firm tick in the box opposite the reply which comes closest to how you have been feeling in the past week. Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought-out response.

Tick only one box in each section

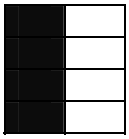
I feel tense or 'wound up':

- Most of the time
- A lot of the time
- Time to time, Occasionally
- Not at all



I feel as if I am slowed down:

- Nearly all the time
- Very often
- Sometimes
- Not at all

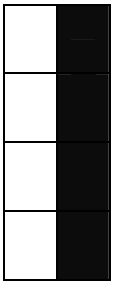


I still enjoy the things I used to enjoy:

- Definitely as much .....
- Not quite so much .....
- Only a little .....
- Hardly at all .....

I get a sort of frightened feeling like 'butterflies' in the stomach:

- Not at all .....
- Occasionally .....
- Quite often .....
- Very often .....



I get a sort of frightened feeling as if something awful is about to happen:

- Very definitely and quite badly .....
- Yes, but not too badly .....
- A little, but it doesn't worry me .....
- Not at all .....

I have lost interest in my appearance:

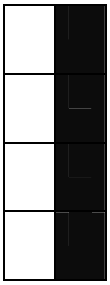
- Definitely .....
- I don't take so much care as I should
- I may not take quite as much care ..
- I take just as much care as ever .....

I can laugh and see the funny side of things:

- As much as I always could .....
- Not quite so much now .....
- Definitely not so much now .....
- Not at all .....

I feel restless as if I have to be on the move:

- Very much indeed .....
- Quite a lot ... .
- Not very much .....
- Not at all .....



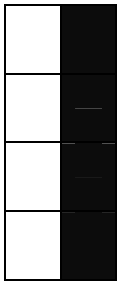
Worrying thoughts go through my mind:

A great deal of the time .....

A lot of the time .....

From time to time but not too often .

Only occasionally .....



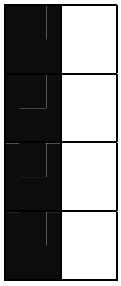
I look forward with enjoyment to things:

As much as ever I did .....

Rather less than I used to .....

Definitely less than I used to .....

Hardly at all .....



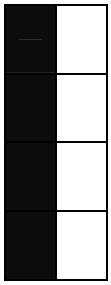
I feel cheerful:

Not at all .....

Not often .....

Sometimes .....

Most of the time .....



I get sudden feelings of panic:

Very often indeed .....

Quite often ...

Not very often .....

Not at all .....

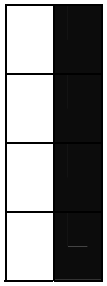
I can sit at ease and feel relaxed:

Definitely .....

Usually .....

Not often .....

Not at all .....



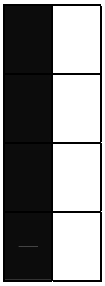
I can enjoy a good book or radio or TV programme:

Often .....

Sometimes .....

Not often .....

Very seldom .....



Appendix 6 - Wilcoxon signed rank test for pre and post QOL CR scores

Test Statistics[a]

	SA PostScore – PreScore
Z	-1.342[b]
Asymp. Sig. (2-tailed)	.180

a. Wilcoxon Signed Ranks Test
b. Based on positive ranks.

Test Statistics[a]

	QOL PostScore - PreScore
Z	-1.342[b]
Asymp. Sig. (2-tailed)	.180

a. Wilcoxon Signed Ranks Test
b. Based on positive ranks.

Test Statistics[a]

	P PostScore - PreScore
Z	.000[b]
Asymp. Sig. (2-tailed)	1.000

a. Wilcoxon Signed Ranks Test
b. The sum of negative ranks equals the sum of positive ranks.

Test Statistics[a]

	OH PostScore - PreScore
Z	-1.414[b]
Asymp. Sig. (2-tailed)	.157

a. Wilcoxon Signed Ranks Test

b. Based on positive ranks.

Test Statistics[a]

	F PostScore - PreScore
Z	-1.000[b]
Asymp. Sig. (2-tailed)	.317

a. Wilcoxon Signed Ranks Test

b. Based on positive ranks.

Appendix 7 - Mann Whitney U test for QOL post CR scores and non-CR scores

Test Statistics[a]

	PF
Mann-Whitney U	20.000
Wilcoxon W	56.000
Z	.000
Asymp. Sig. (2-tailed)	1.000
Exact Sig. [2*(1-tailed Sig.)]	1.000[b]

a. Grouping Variable: group

b. Not corrected for ties.

Test Statistics[a]

	DA
Mann-Whitney U	18.000
Wilcoxon W	33.000
Z	-.313
Asymp. Sig. (2-tailed)	.754
Exact Sig. [2*(1-tailed Sig.)]	.833[b]

a. Grouping Variable: group

b. Not corrected for ties.

Test Statistics[a]

	SA
Mann-Whitney U	13.500
Wilcoxon W	49.500
Z	-1.095
Asymp. Sig. (2-tailed)	.274
Exact Sig. [2*(1-tailed Sig.)]	.354[b]

a. Grouping Variable: group

b. Not corrected for ties.

Test Statistics[a]

	SS
Mann-Whitney U	14.000
Wilcoxon W	50.000
Z	-.902
Asymp. Sig. (2-tailed)	.367
Exact Sig. [2*(1-tailed Sig.)]	.435[b]

a. Grouping Variable: group

b. Not corrected for ties.

Test Statistics[a]

	CinH
Mann-Whitney U	16.000
Wilcoxon W	31.000
Z	-1.265
Asymp. Sig. (2-tailed)	.206
Exact Sig. [2*(1-tailed Sig.)]	.622[b]

a. Grouping Variable: group

b. Not corrected for ties.

Test Statistics[a]

	F
Mann-Whitney U	17.500
Wilcoxon W	32.500
Z	-.392
Asymp. Sig. (2-tailed)	.695
Exact Sig. [2*(1-tailed Sig.)]	.724[b]

a. Grouping Variable: group

b. Not corrected for ties.

Test Statistics[a]

	OH
Mann-Whitney U	17.000
Wilcoxon W	53.000
Z	-.470
Asymp. Sig. (2-tailed)	.638
Exact Sig. [2*(1-tailed Sig.)]	.724[b]

a. Grouping Variable: group

b. Not corrected for ties.

Test Statistics[a]

	QOL
Mann-Whitney U	18.000
Wilcoxon W	54.000
Z	-.361
Asymp. Sig. (2-tailed)	.718
Exact Sig. [2*(1-tailed Sig.)]	.833[b]

a. Grouping Variable: group

b. Not corrected for ties.